REMARKS

Claims 1, 2, 4, and 7 - 13 remain in this application. Claims 1, 2, 4, and 7 - 13 are rejected. Claims 3, 5, and 6 are previously cancelled. Claims 1 and 9 are amended herein to clarify the invention, to express the invention in alternative wording, to address matters of form unrelated to substantive patentability issues, and to overcome the 35 U.S.C. 112, first paragraph bases for rejection of those claims as set forth by the Examiner in the Office Action.

In the Office Action, previous claims 1, 2, 4 and 7 - 13 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The Examiner has contended that the claims contain subject matter not described in the specification in such a way as to enable one skilled in the art to which the present invention pertains to make or use the invention because the specification allegedly does not describe how the virtual three-dimensional model is generated.

Applicants respectfully disagree with the Examiner's position in setting forth the aforesaid rejection. Accordingly, Applicants respectfully traverse this rejection for the following reasons based on the arguments set forth below.

In response to the 35 U.S.C. 112, first paragraph rejection of previous claims 1 - 2, 4 and 7 - 13, Applicants state that the original specification, at page 8, lines 7 - 19, fully and adequately describes and discloses a method by which a

virtual three-dimensional patient model is generated, namely, by using a mathematical image processing algorithm to first form a contour using two-dimensional image data of a patient defect area requiring an implant and a surrounding environment thereto, as first obtained by computer tomography or nuclear magnetic resonance tomography. Applicants submit that a person of ordinary skill in the art at the time the present invention was made would clearly and unambiguously understand the method and its steps based on the description and disclosure recited in the original specification, as discussed above.

In an case, in view of the Examiner's rejection of the claims, Applicants, by their attorney, have reviewed the claims as originally presented and have made certain clarifying amendments to certain of the claims, particularly claims 1 and 9, in view of the foregoing, in order to more particularly point our and distinctly claim the subject matter which the Applicants regard as the invention.

Applicants believe that the original specification is fully enabling with regard to the subject matter being claimed. Applicants further assert and maintain that a person of ordinary skill in the art to which the present invention relates would be aware of and knowledgeable of a large number of image processing methods and techniques which can be utilized to realize the present invention. Such image processing methods and techniques and associated algorithms therefor that are known in the art and that one of ordinary skill in the art would recognize as

representing alternative ways of implementing steps of the present invention include, but are not limited to, filtering, folding (convolution), Boolean algorithms, "Octree Encoding", the "Special Surface Detection Algorithm", the "Three-Dimensional Edge Operator", and the "Matching Cubes Algorithm", as well as the "Marching Cubes" variant thereof.

As a result of the amendments to the claims made herein above, all of the 35 U.S.C. 112, first paragraph based rejections are believed to have been overcome, and the claims, as amended, are now all believed to be in allowable condition. No new matter has been added as a result of the amendments to the claims presented herein.

Therefore, Applicants respectfully request that the 35 U.S.C. 112, first paragraph based rejection be withdrawn and Applicants maintain that such rejection is inapposite to and should not be applied to the claims as amended herein above and pending in the present application after entry of this Amendment.

In the Office Action, previous claims 1, 2, 4 and 7 - 13 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,741,215 to D'Urso ("D'Urso").

The Examiner contends that D'Urso discloses a method of manufacturing a prosthesis that includes all of the steps of the method taught according to the present application, and/or which utilizes the same type of two-dimensional data

as does the method of the present application, and wherein the same method steps are inherently performed.

Applicants respectfully disagree with the Examiner's analysis and conclusion of anticipation with respect to D'Urso.

D'Urso relates to a method for initially producing as near exact an image of a defective region as possible so that in subsequent steps, which are outside of the cope of, and do not actually constitute a part of, the disclosure in D'Urso, an implant device can be fabricated.

In contrast, in the method of the present application, it is an object and a result of the method that the data necessary for subsequently configuring and fabricating the actual implant without requiring the preliminary step needed in D'Urso of first separately mapping and modeling the defective area.

In the method of the present application, a 3D image of the defect-containing area is produced immediately by means of the formation of "isosurfaces", which are areas of identical gray scale values. The 3D image of the defect-containing area is obtained directly by the particular image processing method used.

In contrast to this method of the present application, D'Urso duplicates the defect-containing area in such a manner that the defect-containing region is duplicated or mapped into a contour (i.e., a single height line) that is only two

dimensional, through the use of slices. The slices, or segments, are stacked one on top of another, and a 3D defective region is obtained therefrom only by the use of an interpolative process, which because it involves estimations, contains shortcomings and potential inaccuracies.

The method of D'Urso involves a stereolithographic anatomic modeling method, the steps of which include:

1.) Obtaining data for external and/or internal surface of anatomical structures with defect-containing areas;

2.) Calculating a plurality of two-dimensional sectional images from the data of the anatomical relationships determined;

3.) Preparing a 3D model of the anatomical region containing the defect from the two-dimensional sectional data;

4.) Preparing a physical model of the anatomical relationships from the previously calculated 3D model of the defect-containing area, with the model being constructed layer by layer guided by a stereolithographic method, with the layers being aligned in a position different from that of the two-dimensional layers produced in step (2.). The actual realization of the implant is realized according to D'Urso by the above method through the use of a liquid polymer to form the implant.

According to the above-outlined steps 1 - 4 of the method of D'Urso, a contour of the defect-containing area is produced by means known in the art (see reference at col. 6, lines 25 - 38). In this way, a model, in which an implant that is adapted to the contour can be fitted in an interactive manner. The interactive procedure of D'Urso is completely different from the method of the present application. In D'Urso, an image of the defect-containing area is projected and the contour of an implant is drawn interactively therewith and by a strictly visual method using an interactive input device such as a light-pen, which can be used to track the contour image and convert the information to digital data which is input. In D'Urso, this mapping and digital data input is performed for each contour in which a defect-containing area occurs.

For greater accuracy, one embodiment of the method of D'Urso utilizes a procedure wherein the contour of the implant is determined at the upper and lower layers of the defect-containing area by repeating the measuring procedure for a plane that is orthogonal to the direction of the first layer. The edge of the implant is then fitted to the defect-containing area by a comparison of the previously determined configuration of the implant with the surroundings of the defective area.

Still another embodiment of the method of D'Urso for determining the shape of the implant is based on and utilizes the general symmetry of human anatomy (see reference at col. 8, beginning at line 7). In this embodiment of the

method of D'Urso, a plane of symmetry is established, however, the reference does not disclose how it is optimized. Values of +1 and -1 are assigned to data for bones respectively to the right and left of the plane of symmetry. According to this embodiment of the method, after a specular reflection at the plane of symmetry, the assigned values are summed and there is an expectation that at those locations where there is a defect in the bone, the implant contour will produce values of +1.

A general characteristic of the several embodiments of the method of D'Urso is that they are interactive processes which are subjective and incapable of being reproduced, so that an exact shape of the implant to be constructed is not possible and cannot be exactly replicated.

The method of D'Urso represents the state of the prior art as it existed before the present application, as has been mentioned by applicants themselves in the present application, and reflects all of the limitations inherent in the prior art, as referred to by the applicants.

A 3D implant having all of the features of one produced according to the method of the present application cannot be produced according to the interactive 3D adjusting methods of D'Urso.

In a broad overall sense, moreover, D'Urso discloses the preparation of a model of a defect-containing area, but does not disclose the actual method and steps for constructing an actual 3D implant, whereas the present application teaches and

discloses a method for the construction of an exact 3D implant and is not limited to a method of preparing a mapping of a two-dimensional contour of a defect-containing region. D'Urso does not teach, disclose, or suggest a method having steps relating to the formation or fitting of an implant using strictly computer based techniques, as does the present application.

Therefore, in summary, applicants respectfully submit that D'Urso cannot be said to anticipate the method of the present application under 35 U.S.C. 102(b). Accordingly, Applicants request that the 35 U.S.C. 102(b) rejection be withdrawn; and Applicants further maintain that the rejection is not applicable to the claims as amended by this Amendment, and further in view of the associated remarks presented herein in accompaniment to such amendments to the claims, so that the rejection should not be applied to any of the amended claims.

No additional claims fees are due with the filing of this Amendment.

Applicant respectfully requests a one month extension of time for responding to the Office Action. Please charge the fee of $120.00 for the extension of time to Deposit Account No. 10-1250.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

No other fees are believed due with the filing of this Amendment. If, however, any other fees are due, or if Applicants are entitled to a refund of any previously made overpayments, they should be respectively charged and credited to Deposit Account No. 10-1250.

Respectfully submitted,
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